



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/660,444

09/11/2003

Andrzej Chanduszeko

NMT-015

4893

22832

7590

03/10/2008

Kirkpatrick & Lockhart Preston Gates Ellis LLP
(FORMERLY KIRKPATRICK & LOCKHART NICHOLSON GRAHAM)
STATE STREET FINANCIAL CENTER
One Lincoln Street
BOSTON, MA 02111-2950

EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

03/10/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/660,444	Applicant(s) CHANDUSZKO ET AL.	
	Examiner DIANE YABUT	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,34-42 and 60-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31,34-42 and 60-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/01/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received on 10/29/2007.

The examiner acknowledges the amendments to the claims.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 11/01/2007 is considered. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 31, 34-35, and 60-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Ginn** (U.S. Patent No. **6,702,835**) in view of **Roe** (U.S. Patent No. **6,780,197**).

Claims 31, 34-35, and 60-63: Ginn discloses a delivery member comprising a first member comprising a first end portion and a second free end portion **16**, introducing said second free end portion of said first member through an opening **94** of a patent foramen ovale from the right atrial side to the left atrial side, contacting said second free end portion with a left atrial side of tissue of a septum primum **95**, introducing a hole

through the septum primum from the right atrial side of the septum primum to the left atrial side of the septum primum, and introducing an occlusion device **40** or septal occluder and suture **30** for occluding said patent foramen ovale through said hole in said septum primum along with an apparatus **30** that joins tissue (Figures 5A-8B; col. 7, line 60 to col. 8, line 9).

Ginn discloses the claimed invention except for the first member being flexible and the second free end portion being withdrawn from the left atrial side, as well as a second flexible member.

Roe teaches flexible members (“positioning elements”) with free end portions **64** that contact one side of tissue **98** to be occluded, with the second end portions being placed on the opposite side of tissue (near **96**), which are subsequently withdrawn from the heart (Figures 4D-4F; col. 3, lines 38-46). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Ginn by contacting tissue with a flexible member that is withdrawn afterwards, as taught by Roe, prior to introducing a hole and occlusion device in order to provide a tactile indication of the position of the delivery member as well as to assist in presenting or stabilizing the tissue to get pierced or occluded (col. 9, lines 1-8). Although the flexible member is not spiral-shaped, it would have been obvious to one of ordinary skill in the art to modify Ginn with a spiral-shaped flexible member since coils, spirals, and helical configurations are well known shapes for elements that effectively approximate tissue.

4. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over over **Ginn** (U.S. Patent No. **6,702,835**) in view of **Roe** (U.S. Patent No. **6,780,197**), as applied to claim 35 above, and further in view of **Sawyer** (U.S. Patent No. **5,749,895**).

Claim 36: Neither Ginn nor Roe expressly discloses a tissue welding apparatus.

However, use of a tissue welding apparatus is well known in the art, as evidenced by Sawyer (see abstract). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a tissue welding apparatus, as taught by Sawyer, to Ginn and Roe in order to more effectively ensure a tight occlusion of the PFO defect.

5. Claims 37 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Roe** (U.S. Patent No. **6,780,197**) in view of **Das** (U.S. Patent No. **5,334,217**).

Claims 37 and 40: Roe discloses introducing a delivery member **12** for delivering a plurality of flexible members **64**, introducing at least one of said flexible members through the opening of a blood vessel, contacting the at least one of said flexible members with a distal side **98** of tissue, withdrawing the at least one of said flexible members from the distal side, and withdrawing said delivery member including said plurality of flexible members from the body, and an apparatus **26** for joining tissue (Figures 4A-4F; col. 3, lines 39-46).

Roe discloses the claimed invention except for the flexible members being hexagonally shaped and being introduced into a patent foramen ovale.

Das teaches a septal closure device and method using flexible members **24C** being introduced into a patent foramen ovale, which are hexagonally shaped (Figure

5C). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Roe with Das, since it is also a closure method and the hexagonally shaped members provide bends which permit the frame to be collapsed more readily into a delivery catheter (col. 5, line 54 to col. 6, line 6).

6. Claims 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Roe** (U.S. Patent No. **6,780,197**) in view of **Das** (U.S. Patent No. **5,334,217**), as applied to claim 37 above, and further in view of **Ginn** (U.S. Patent No. **6,702,835**).

Claims 38-39: Roe and Das disclose the claimed device, except for providing a cutting member and introducing a hole in said septum primum, and providing an occlusion device for occluding said patent foramen ovale through said hole in said septum primum, wherein the occlusion device is selected from the group consisting of a septal occluder, suture, staple, or adhesive.

Ginn teaches a cutting member **16** and introducing a hole in said septum primum, and providing an occlusion device or septal occluder **40** and suture **30** for occluding said patent foramen ovale through said hole in said septum primum (Figures 5C-5D). It would have been obvious to one of ordinary skill in the art at the time of invention to introduce a hole in the septum primum with a cutting member for a septal occluder, as taught by Ginn, to Roe and Das in order to facilitate effectively approximating and occluding the septal tissue with a septal occluder.

7. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Roe** (U.S. Patent No. **6,780,197**) in view of **Das** (U.S. Patent No. **5,334,217**), as applied to claim 40 above, and further in view of **Sawyer** (U.S. Patent No. **5,749,895**).

Claim 42: Neither Roe nor Das expressly discloses a tissue welding apparatus.

However, use of a tissue welding apparatus is well known in the art, as evidenced by Sawyer (see abstract). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a tissue welding apparatus, as taught by Sawyer, to Roe and Das in order to more effectively ensure a tight occlusion of the PFO defect.

Response to Arguments

8. Applicant's arguments with respect to claims 31, 34-42, and 60-64 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

Art Unit: 3731

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734
/Todd E Manahan/

Application/Control Number: 10/660,444

Page 8

Art Unit: 3731

Supervisory Patent Examiner, Art Unit 3731